DATE OUT: January 6, 2012

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI [X]; MUP [ ]; EUP []
BARCODE NO.: 397282 **REG. /FILE SYMBOL NO.:** 5481-219
PRODUCT NAME: 1-Naphthaleneacetic Acid
MRID No.: No studies are submitted
COMPANY NAME: AMVAC Chemical Corporation
ACTION CODE: 676

FROM: Nina Simeonova, Chemist
Product Chemistry Team
Risk Management and Implementation Branch 5
Product Re-evaluation Division (7508P)

TO: Veronica Dutch, CRM
Risk Management and Implementation Branch 5
Product Re-evaluation Division (7508P)

INTRODUCTION:

With this resubmission the registrant provided revised basic CSF dated 1/5/12 and the alternate 1 CSF dated 12/22/11 in support of the reregistration of1-Naphthaleneacetic Acid, EPA Reg. No. **5481-219**.

FINDINGS:

1. The resubmitted basic CSF dated 12/22/11 and the alternate 1 CSF dated 1/5/12 are revised as requested. The identification of the producers of the TGAI is complete. The nominal concentration of the active ingredient is in compliance with the ingredient statement of the label. The self-proposed certified limits according to 40CFR§158.350(c) are acceptable.

2a. The ingredient statement of the label is acceptable. It is supported by the revised CSFs. It is in compliance with the requirements of 40CFR§156.10(g) and PR Notice 91-2. (The name of the product in Box 3 is not exactly the same as on the label);
2b. The physical/chemical properties of the product do not require precautionary statements in the section "Physical or Chemical Hazards";
2c. The statements in Section "Storage and Disposal" are in compliance with 40CFR§156.10(i) (2) (ix). It appears that they are not revised for compliance with PR Notice 2007-4. PRD defers the acceptability of this section to RD.

Note to CRM/PM:

With this resubmission the registrant provided consistent data on the label and on the CSFs that the nominal percent of the active ingredient in Reg. No. 5481-219 is 95.5 %. In OPPIN it is 95.0%.

CONCLUSIONS:

The registrant has now satisfied the product chemistry data requirements for the reregistration of 1-Naphthaleneacetic Acid, EPA Reg. No. 5481-219. The label issues may be resolved during the label review.

DATE OUT: January 11, 2010

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI [ ]; MUP [x]; EUP []
BARCODE NO.: 366954 **REG. /FILE SYMBOL NO.:** 5481-219
PRODUCT NAME: 1- Naphthaleneacetic Acid
MRID NOS.: 405229-01, 405229-03, 435804-02, 438777-01, 438777-02, 439983-01, 439983-02, 451430-02 and 474786-11
COMPANY NAME: AMVAC CHEMICAL CORPORATION **ACTION CODE:** 676

FROM: Nina Simeonova, Chemist
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TO: Veronica Dutch, CRM
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INTRODUCTION:

A Reregistration Eligibility Decision (RED), Case # 3079, was issued in May 2004 and was revised in October 2007 for the Technical Grade Active Ingredient (TGAI) Naphthaleneacetic Acid, its Salts, Ester and Amide. According to the RED, the generic data base supporting the reregistation of Naphthaleneacetic Acid, its Salts, Ester and Amide has been reviewed and found to be substantially complete.

In the 8-month response to the Naphthalene Acetic Acid, its Salts, Ester and Amide Reregistration Eligibility Decision, AMVAC Chemical Corporation submitted a basic (dated 1/25/01) and an alternate (dated 5/25/2000) Confidential Statements of Formula (CSFs), label (received at EPA on 10/9/08) and a data matrix (not dated). Only the study MRID # 474786-11 titled "UV/Visible Absorption of 1- Naphthaleneacetic Acid and its Sodium, Potassium and Ammonium Salts" is submitted in this data package. According to the bean sheet the applicant requests to share data with the products EPA Reg. No. 5481-337 and 5481-498. MRID # 405229-01, 438777-01, 438777-02, 435804-02 and 474786-11 are listed in the bean sheet as sources of Product Chemistry data to support the application for reregistration of 1- Naphthaleneacetic Acid Technical, EPA Reg. No. 5481-219.

FINDINGS:

1. 1-Naphthaleneacetic Acid, EPA Reg. No. 5481-219, basic and alternate formulation, is a TGAI. It contains 95.5 % 1-Naphthaleneacetic Acid as its active ingredient. It is used as a source of the active ingredient in end-use products with [redacted]

2. The producer of the TGAI 1- Naphthaleneacetic Acid, EPA Reg. No. 5481-219 is not identified properly in the basic CSF. The data in Box 2 and Column 11 for the active ingredient are inconsistent. The Establishment No. is not provided in Box 2. The CAS # of the active ingredient in the alternate formulation is not correct. The self-proposed certified limits (40 CFR§158.350c) for the active ingredient and the upper self-proposed certified limits for the manufacturing impurities (Column 14a) are acceptable. They are based on the results from the preliminary analysis. The CSFs are unacceptable, but upgradeable.

3. No PC studies (except for MRID 474786-11) are included in DP # 366954. The Data Matrix, OPPIN Query and Documentum were used to find and review the product chemistry studies which support the reregistration of 1-Naphthaleneacetic Acid, EPA Reg. No. 5481-219. The data requirements Product Identity and Composition (40CFR§158.320), Description of Materials used to produce the Product

Manufacturing process information may be entitled to confidential treatment

(40CFR§158.325), Description of Production Process, (40CFR§158.330) and Discussion of Formation of Impurities (40CFR§158.340) are addressed in MRID No. 405229-01, 438777-01 and 439983-01. The data about Preliminary Analysis (40CFR§158.345), Certified Limits (40CFR§158.350) and Enforcement Analytical Method (40CFR§158.355) are found in MRID 438777-02 and 439983-02. The results from determination of the Physical/Chemical Characteristic (40CFR§158.310, Group B) Color, Physical State, Odor, Melting Point, Bulk Density, Solubility, Vapor Pressure, Dissociation Constant and pH are provided in MRID 405229-03. Additional data about Explodability and Chemical Incompatibility are found in the MSDS from the producer attached in MRID 451430-02. MRID 474786-11 contains data about UV/Visible Absorption of the TGAI and its water soluble salts. The results from testing Storage Stability and Corrosion Characteristics (40CFR§158.310, Group B) at normal storage conditions for 22 months (from March 1993 to May 1995) are provided in MRID 435804-02. The study is not in compliance with the requirements of OPPTS Guidelines 830.6317 and 830.6320. Three samples are analyzed for the whole term at storage, but the conclusion " 1-Naphthaleneacetic Acid is stable for at least 22 months under normal warehouse storage conditions in the original container" is supported by the results. The study is acceptable. The registrant has satisfied the applicable PC data requirements.

4. The label's ingredient statement is not in compliance with the CSF. The nominal concentration of the active ingredient on the label is 95.5 % and 95.0 % in the CSFs. The physical/chemical properties of 1-Naphthaleneacetic Acid TGAI do not trigger statements in the Section "Physical or Chemical Hazards". The statements in Section "Storage and Disposal" are in compliance with 40CFR§156.10(i) (2) (ix) and therefore acceptable.

   NOTE TO PM:

   The studies used in this report are not included in DP # 366954 with the exception of MRID 474786-11. The list of studies in the attached data matrix is correct. More studies submitted for the registration of EPA 5481-219 are found in OPPIN. The studies were found and reviewed in Documentum (except for MRID 474786-11).

CONCLUSIONS:

The registrant will completely satisfy the PC data requirements after the resolution of the deficiencies in the CSFs according to **Finding 2**. The producer/supplier is not properly identified in the basic CSF dated 25/01/01. There is inconsistency in the content of Box 2 and Column 11 (the row of the active ingredient). The Establishment Number is not provided in Box 2. The CAS # of the active ingredient in the alternate CSF dated 05/05/00 is not correct.

Product Chemistry Data

Group A: Guidelines Series 830.1550 - 830.1800 (40 CFR §158.320 - 158.355)

Product Identity, Composition, and Analysis

GUIDELINE REFERENCE NO. (GRN)/ TITLE 830	40 CFR §	MRID Number	Data Fulfilled
830.1550 Product Identity and Composition	158.320	405229-01, CSF	Y
830.1600 Description of Materials Used to Produce the Product	158.325	405229-01	Y
830.1620 Description of Production Process	158.330	405229-01, 438777-01, 439983-01	Y

830.1650 Description of Formulation Process	158.335		N/A
830.1670 Discussion of Formation of Impurities	158.340	405229-01, 438777-01, 439983-01	Y
830.1700 Preliminary Analysis	158.345	438777-02, 439983-02	Y
830.1750 Certified Limits	158.350	438777-02, 439983-02	Y
830.1800 Enforcement Analytical Method	158.355	438777-02, 439983-02	Y

Subgroup B: Series 830.6302 - 7950 (40 CFR §158.310)
Physical and Chemical Properties

GUIDELINE REFERENCE NO. (GRN)/ TITLE 830	VALUE OR QUALITATIVE DESCRIPTION	MRID number	Data Fulfilled
.6302 Color	White	405229-03	Y
.6303 Physical State	Amorphous or crystalline powder	405229-03	Y
.6304 Odor	Odorless	405229-03	Y
.6313 Stability to normal and elevated temperatures, metals a metal ions	Stable under normal use and storage conditions	MSDS in MRID 451430-02	Y
.6314 Oxidation/Reduction: Chemical Incompatibility	Will react with bases to form water soluble salts	MSDS in MRID 451430-02	Y
.6315 Flammability/Flame Extension	Not applicable	MSDS in MRID 451430-02	Y
.6316. Explodability	Not determined, but not expected to be explosive due to mechanical impact	MSDS in MRID 451430-02	Y
.6317 Storage Stability	Stable for at least 22 months under normal warehouse storage conditions in the original	435804-02	Y

	container		
.830.7050 UV/Visible Absorption	217, 272 and 282 nm @ pH ~7; 212, 271 and 280 nm@ pH< 2; 209, 272 and 282 nm@ pH > 10.	474786-11	Y
.6318 Viscosity			N/A
.6319 Miscibility			N/A
.6320 Corrosion Characteristics	Not corrosive to the packaging material @ normal storage conditions	435804-02	Y
.6321 Dielectric Breakdown Voltage			N/A
.7000 pH	3.45 (1 % slurry)	405229-03	Y
.7300 Density/Relative Density/Bulk Density	3.75 lb/gal (packed bulk density)	405229-03	Y
.7200 Melting Point/ Melting Range	131-133 °C	405229-03	Y
.7370 Dissociation Constant	$3.16.10^{-4}$	405229-03	Y
.7840 Solubility .7860	In water: 0.042g/100g @ 26 °C; In Xylene: 5.55 g/100g @ 26 °C.	405229-03	Y
.7950 Vapor Pressure	0.30 mm Hg@ 26 °C	405229-03	Y

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable; G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived

Analytical methods:

- For the active ingredient: HPLC with internal standard p- CPA and UV-detection or HPLC with external standard and UV-detection;
- For the manufacturing impurities: Cl' or SO4'' titration, extraction. Karl-Fisher titration.